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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,091	02/05/2001	Dusan Pavcnik	PA-5213-CIP	2451

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EXAMINER

BLANCO, JAVIER G

ART UNIT PAPER NUMBER

3738

DATE MAILED: 09/11/2002

22

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/777,091

Applicant(s)

PAVCNIK ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-47 is/are pending in the application.
- 4a) Of the above claim(s) 7-9, 14, 17, 18, 23, 24, 31-35 and 42-45 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-6, 10-13, 15, 16, 19-22, 25-30, 36-41, and 46-47 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7-18.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Election/Restrictions***

1. Applicant's election with traverse of Species K (embodied by Figures 21, 22, 23, 24, 25, 26, 26A, 27, and 50) in Paper No. 21 is acknowledged. Applicants regard claims 1-6, 10-13, 15-16, 19-22, 25-30, 36-41, and 46-47 to read on Species K. The traversal is on the ground(s) that the division of disclosed embodiments is unnecessary to enable the Examiner to conduct a reasonable search. This is not found persuasive because the amount of species present in the application will create a burdensome search for the Examiner.

The requirement is still deemed proper and is therefore made FINAL.

2. Claims 7-9, 14, 17, 18, 23, 24, 31-35, and 42-45 withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a non-elected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 21.

### ***Claim Objections***

3. Claims 27 and 28 are objected to because of the following informalities: improper claim numbering. As seen in page 45 of the specification, claims 27 and 28 are improperly numbered. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

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pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 1-6, 10-13, 15, 16, and 36-41 are rejected under 35 U.S.C. 112, first paragraph, because the best mode contemplated by the inventor has not been disclosed. Evidence of concealment of the best mode is based upon the lack of a support structure (i.e., frame) to hold/support the claimed plurality of leaflets or the claimed covering. **It should be noted that the elected species (embodied by Figures 21, 22, 23, 24, 25, 26, 26A, 27, and 50) shows a covering/plurality of leaflets attached to a frame.**

6. Claims 4, 19-22 and 25-30 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Regarding claim 4, the claim limitation "overhanging material" (see line 2) was not disclosed/described in the specification.

b. Regarding claim 19, the claim limitation "includes one or more flexible materials" (see lines 8-9) was not disclosed/described in the specification.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1-6, 10-13, 15, 16, 19-22, 25-30, 46, and 47 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

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- a. Regarding claim 1, the claim limitation “**or another** of the plurality of leaflets” (see line 4) is indefinite since it gives the impression that there are more than one plurality of leaflets. Also, the claim limitation “the outer edge **of each** of the plurality of leaflets” (see line 10) is indefinite since it gives the impression that there is more than one plurality of leaflets. Also, the claim limitation “**at least substantially** occlude fluid flow” (see lines 7-8) renders the claim indefinite since it gives the impression that the plurality of leaflets will allow some fluid to pass “in a second direction opposing the first direction”.
- b. Claim 2 recites the limitation “The vascular valve” in line 1. There is insufficient antecedent basis for this limitation in the claim.
- c. Claim 2 recites the limitation “the free edge” in line 2. There is insufficient antecedent basis for this limitation in the claim.
- d. Regarding claim 5, the claim limitation “**a wire to and around** which the bodies of the leaflets are secured” (see lines 1-2) is vague and renders the claim indefinite.
- e. Claim 6 recites the limitation “the covering” in line 1. There is insufficient antecedent basis for this limitation in the claim.
- f. Claim 10 recites the limitation “the covering” in line 1. There is insufficient antecedent basis for this limitation in the claim.
- g. Claim 11 recites the limitation “the extracellular collagen matrix” in lines 1-2. There is insufficient antecedent basis for this limitation in the claim.
- h. Claim 19 recites the limitation “the second end” in line 5. There is insufficient antecedent basis for this limitation in the claim.

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- i. Regarding claim 29, the claim limitation “a generally flat plane” is vague and renders the claim indefinite. The plane is either flat or other configuration; but can’t be “generally flat”.
- j. Regarding claim 46, the claim limitation “**or another** of the plurality of leaflets” (see line 7) is indefinite since it gives the impression that there is more than one plurality of leaflets. Also, the claim limitation “**at least substantially** occlude fluid flow” (see line 13) renders the claim indefinite since it gives the impression that the plurality of leaflets will allow some fluid to pass “in a second direction opposing the first direction”.
- k. Claim 47 recites the limitation “the second end” in line 5. There is insufficient antecedent basis for this limitation in the claim. Also, the claim limitation “**at least substantially** reduce retrograde flow” (see lines 24-25) renders the claim indefinite since it gives the impression that the pair of leaflets will allow some fluid to pass in a “retrograde” direction.

### ***Claim Rejections - 35 USC § 102***

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in-

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or

(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

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10. Claims 36-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Camilli (US 5,607,465 A; cited in Applicant's IDS). Camilli discloses an implantable vascular valve comprising a support or valve body 1 bent into three turns 5, 6, and 6', hooks or barbs 7, and a covering or mobile plate 2, wherein the covering has an opening in order to regulate blood flow (see Figures 1-4; see Abstract; see column 3, lines 2-3 and lines 65-67; column 4, lines 1-7, lines 19-23, and lines 39-57; see entire document).

11. Claims 1-5, 10-12, and 36-41 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Cox (US 5,713,950 A; cited in Applicant's IDS). Cox discloses replacement heart valves comprising a covering or plurality of leaflets made from a collagen material (i.e., small intestinal submucosa or SIS; see Figures 1-8; see Abstract; see column 25, lines 4-10). The covering or plurality of leaflets define arched or arcuate surfaces ending in an orifice (see Figures 2-6) to permit fluid flow in a first direction while occluding fluid flow in a second direction (see Figures 2-6; see column 21, lines 25-36; column 23, lines 30-39). The covering or plurality of leaflets is sutured to either a valve annulus or to an annuloplasty ring (see column 21, lines 23-24; column 23, lines 28-29).

12. Claims 1-5, 12, 15, 16, 19-22, 25, 28, "27", "28", 29, 36-41, and 46 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Bessler et al. (US 5,855,601 A; cited in Applicant's IDS). Bessler et al. disclose a heart valve comprising a frame (i.e., self-expanding stent 21 or 32) and a valve member/covering 22 (or 35) shaped as a plurality of arcuate and flexible leaflets 24 (see Figures 1, 2, and 4; see column 3, lines 65-67; column 4, lines 1-3; column 5, lines 21-27 and lines 34-38; column 6, lines 3-7). The valve member/covering 22 (or 35) is made of a biocompatible material (see column 6, lines 19-31). The plurality of leaflets defines an orifice

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which open in response to blood flow in one direction and close in response to blood flow in the opposite direction (see column 3, lines 65-67; column 4, line 1). The stent is formed in a zig-zag or serpentine configuration (see Figures 1, 4, and 6; see column 5, lines 54-55) and may comprise a plurality of barbs (see Figure 6) for fixing the valve in a desired position (see column 4, lines 12-14). The straight portions of the stent are joined by bends 54 (see column 5, lines 55-58).

***Claim Rejections - 35 USC § 103***

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

14. Claims 10, 11, 26, 27, and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bessler et al. (US 5,855,601 A; cited in Applicant's IDS) in view of Cox (US 5,713,950 A; cited in Applicant's IDS). Bessler et al. disclose the invention as claimed except for disclosing the covering or plurality of leaflets as comprising small intestinal submucosa. However, Cox discloses a valve with leaflets comprising small intestinal submucosa in order to eliminate the risk of immune rejection and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers (see column 14, lines 34-42). It would have been obvious to one of ordinary skill in the art at the time the invention was made to have combined the teaching of using a covering/plurality of leaflets comprising small intestinal submucosa, as taught by Cox, with the valve of Bessler et al., in order to eliminate the risk of immune rejection



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and to eliminate the need to use fixation treatment to reduce the antigenicity of tissue from animals or cadavers.

*Allowable Subject Matter*

15. Claims 6, 13, and 30 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

*Conclusion*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 703-605-4259. The examiner can normally be reached on M-F (7:00 a.m.-4:30 p.m.), first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 703-308-2111. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9302 for regular communications and 703-872-9303 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.



JGB

September 9, 2002



David H. Willse  
Primary Examiner